

**REMARKS**

Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested. Claims 20-37 are pending and at issue.

**Rejection Under 35 U.S.C. §103(a)**

Claims 20-37 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,943,590 (“the ‘590 Patent”) in view of U.S. Patent No. 5,846,982 (“Audia”) and Schaller et. al., *J. Neuropsychiatry and Clinical Neurosciences*, 11:4, Fall 1999 (“Schaller”). The Examiner contends that Boegesoe teaches a method for treating depression with escitalopram by inhibiting the uptake of serotonin, and that Audia teaches that attention deficit hyperactive disorder (ADHD) can be treated with compounds that inhibit serotonin reuptake. The Examiner further contends that Schaller teaches that ADHD increases one’s risk for major depression and anxiety disorder. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to treat ADHD with escitalopram, since both ADHD and depression are treatable by inhibiting the uptake of serotonin. The Examiner further contends that Schaller provides the motivation to administer escitalopram to a patient with ADHD in view of the reasonable expectancy of decreasing the patient’s risk of depression.

Applicants respectfully traverse this rejection, and request reconsideration.

None of the cited references would have provided one of ordinary skill in the art with the motivation or a reasonable expectation of success for treating ADHD with escitalopram. As acknowledged by the Examiner, the ‘590 Patent does not “disclose a method of ... treating attention deficit hyperactivity disorder with escitalopram.” (February 9, 2006 Office Action, page 3, third paragraph).

The Examiner cites Audia as teaching that ADHD can be treated with a compound that inhibits serotonin uptake. But this is not the case. Audia only teaches that the tetrahydropyridinyl- and piperidinyl-indoles and benzothiophenes disclosed therein are useful for treating numerous

disorders including ADHD. In particular, Audia states that the “present treatment methods” are useful in treating various disorders, including ADHD:

**The present treatment methods** are useful for treating many other diseases, disorders and conditions as well, as set out below ...

Depression, ..., migraine[,], pain, ... bulimia, ... premenstrual syndrome or late luteal phase syndrome, alcoholism, ... tobacco abuse, ... panic disorder, ..., anxiety, ..., post-traumatic disorder, ... memory loss, ... dementia of aging, ... social phobia, ... attention deficit hyperactivity disorder, ... disruptive behavior disorders, ... impulse control disorders, ... borderline personality disorder, ... chronic fatigue syndrome[,], premature ejaculation, ... erectile difficulty, ... anorexia nervosa, ... disorders of sleep, ... autism[,], mutism[, and] trichotillomania

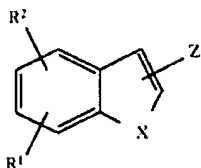
(Audia at col. 52, line 48 to col. 53, line 7 (emphasis added)). All the treatment methods disclosed in Audia require administration of a tetrahydropyridinyl- or piperidinyl-indole or a benzothiophene:

The present invention provides a method for the inhibition of serotonin reuptake comprising administering to a mammal in need of such inhibition a pharmaceutically effective amount of tetrahydropyridinyl- and piperidinyl-indoles and benzothiophenes of Formula I.

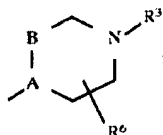
(Audia at col. 1, lines 46-50), and

Numerous other treatment methods carried out by administration of the compounds of Formula I will be set out in detail below.

(Audia at col. 52, lines 1-3). Accordingly, Audia only teaches that the tetrahydropyridinyl- and piperidinyl-indoles and benzothiophenes of Formula I described therein are useful in treating ADHD. Escitalopram is not a tetrahydropyridinyl- or piperidinyl-indole or a benzothiophene and does not fall within Formula I, as shown below:

Audia Formula I

where Z is a structure of formula



where X is S or NR<sup>4</sup>.

(Audia at col. 1, line 46 to col. 2, line 16).

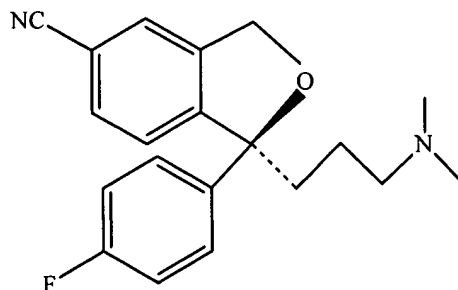
Furthermore, there is no disclosure nor any suggestion in Audia that serotonin reuptake inhibitors other than the compounds of Formula I are useful in treating ADHD. Therefore, Audia does not disclose or suggest that the structurally different compound escitalopram would be effective in treating ADHD, let alone that serotonin reuptake inhibitors in general would be effective in treating this disorder.

Additionally, the Examiner argues that Schaller provides motivation for treating ADHD with escitalopram because ADHD increases one's risk of depression, and escitalopram is known to be an effective antidepressant. The Examiner's logic is incorrect. It does not logically follow that just because disease A increases the risk of disease B, a drug that is effective in treating disease B will be effective in treating disease A. An analogous example is that diabetes increases one's risk of heart disease. According to the Examiner's logic, since diabetes increases one's risk of heart disease, aspirin, which is effective in treating heart disease, must also be effective in treating diabetes. However, it is well known in the art that while aspirin can be used to treat heart disease, aspirin is not effective in treating diabetes. Similarly, just because escitalopram is known to treat depression, there is no reasonable expectation that escitalopram will be effective in treating ADHD, even though ADHD may increase the risk of depression.

Escitalopram

I

(i)



Furthermore, when Schaller discusses a proposed treatment for patients suffering from ADHD, major depression and anxiety, it states that each indication should be treated separately:

[W]e are proposing patients with such co-morbidities should have their [major depression] treated first, their anxiety disorder next, and finally be offered a non-combination, low potency stimulant for ADHD.

(Schaller, first paragraph). Schaller reports that a patient treated with the selective serotonin reuptake inhibitor (and anti-depressant) sertraline still exhibited symptoms of ADHD. As a result, the patient was also treated with a stimulant, methylphenidate. By finding that a selective serotonin reuptake inhibitor was ineffective in treating ADHD and suggesting the use of a stimulant for this disorder, Schaller teaches away from treating ADHD with a selective serotonin reuptake inhibitor, such as escitalopram. Therefore, Schaller does not disclose or suggest that escitalopram would be effective for treating ADHD.


For the foregoing reasons, the '590 Patent, Audia and Schaller fail to render obvious claims 20-37. Therefore, applicants respectfully request withdrawal of this rejection.

### **Conclusion**

In view of the above remarks, applicants believe that each of the pending claims in this application is in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: August 7, 2006

Respectfully submitted,

By   
Dianna Goldenson

Registration No.: 52,949  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant